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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OLIFF & BERRIDGE, PLC
P.O. BOX 19928
ALEXANDRIA, VA 22320

EXAMINER

RODRIGUEZ, CRIS LOIREN

ART UNIT PAPER NUMBER

3763

17

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/826,207

Applicant(s)

DEVONEC, MARIAN

Examiner

Cris L. Rodriguez

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-50, 53-112 and 121-140 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 47, 84-97, 134 and 135 is/are allowed.
- 6) ☒ Claim(s) 21-46, 48-50, 53-83, 98-112, 121-127, 129-133 and 136-140 is/are rejected.
- 7) ☒ Claim(s) 128 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims 125-128 is withdrawn in view of the newly discovered reference(s) to Torchio. Rejections based on the newly cited reference(s) follow. The amendment to claim 125 changes the scope of the claim; therefore a rejection has been made based on those changes.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 21-35, 41-46, 48-50, 53-71, 77-83, 98-112, 121-124, 133, and 136-140 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilber (US 5,059,169) in view of Wolff et al (US 5,545,208).

Zilber discloses a prostatic stent, for obstruction due to prostate gland enlargement, having a non-biodegradable element (figs. 1-5) to be retained in the prostatic portion, and a withdrawal thread 22. Figure 1-2 shows a texturized fabric outer continuous layer 20. However, Zilber fails to disclose a cytoreduction agent positioned along the element 10,30.

Wolff teaches a stent that can be used to treat the prostate gland due to chronic closure. The stent contains a cytoreductive agent such as an antimitotic agent

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(Col. 5 lines 56-64). Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Wolff's cytoreductive drugs onto Zilber's prostatic stent. Doing so would have locally treated the obstruction caused by the prostate enlargement, and inhibited its growth.

4. Claims 38, and 74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilber in view of Wolff et al, and further in view of Silvestrini (US 5,234,456).

Zilber/Wolff discloses the invention substantially as claimed. However, Zilber/Wolff fails to disclose that the covering substrate is hydrophilic and expandable.

Silvestrini teaches a hydrophilic stent, to be used in the urethral and ureteral ducts (col. 1, lines 56-58) that can carry drugs to be released once inserted. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Silvestrini's hydrophilic material into Zilber/Wolff's stent. Doing so would have expanded the urethra's lumen more once in contact with the biological fluids.

5. Claims 36, 37, 39, 40, 72, 73, 75, and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zilber in view of Wolff et al, and further in view of Yamamoto et al (US 4,676,782).

Zilber/Wolff discloses the invention substantially as claimed. However, Zilber/Wolff fails to disclose the internal core being off-centered in relation to one another, the substrate is expandable and is radially inscribed within the outer surface of the element, a sheath made of a synthetic foam, and the substrate having a plurality of channels.

Yamamoto teaches a sleeve-like tissue interface device, (figs. 4b, 5, 6a-6d), having the internal core off-centered in relation to one another, the substrate being expandable and is radially inscribed within the outer surface of the element, a sheath made of a synthetic foam, and the substrate having a plurality of channels. Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Zilber/Wolff's stent with Yamamoto's devices configurations. Doing so would have provided alternate embodiments for draining body fluids, and expanding the prostatic area with such configurations.

6. Claims 125-127, 129-132 are rejected under 35 U.S.C. 103(a) as being unpatentable over Torchio(US 5,514,178) in view of Wolff et al.

Torchio discloses a stent device and method for treating an obstruction. The stent having a non-biodegradable tubular element 1 designed to be placed in at least an obstructed part of a natural lumen upstream of the sphincter (figs. 6, 12, and 17); the element being retained in the downstream direction by the sphincter, and in the to upstream direction by retaining means 4 linked to the element and to be placed in the lumen downstream of the sphincter. The stent is capable of treating an obstruction in the prostatic portion of a male urethra. However, Torchio fails to disclose a cytoreduction agent positioned along the element.

Wolff teaches a stent that can be used to treat the prostate gland due to chronic closure. The stent contains a cytoreductive agent such as an antimetabolic agent (Col. 5 lines 56-64). Given the teachings, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use Wolff's cytoreductive

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drugs onto Torchio's stent. Doing so would have locally treated the obstruction in the natural lumen, and inhibited its growth.

Allowable Subject Matter

7. Claim 128 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. Claims 47, 84-97, 134, and 135 are allowable over the prior art of record.

Response to Arguments

9. Applicant's arguments filed November 10, 2003 have been fully considered but they are not persuasive.

In regards to applicant's arguments to the claims amended language, which recites that "the reductive effect is through direct contact with cells of the obstruction, and that, even without removing the device from the lumen, the reductive effect ceases when the direct contact ceases", are not found persuasive because it is inherent in the cytoreductive action and effect upon the treated area. First, the direct contact with the obstruction cells can be affected by the type of medication and its duration, or if the medicated stent is removed from the natural lumen, and second, upon cytoreduction effect the obstruction in the natural lumen will shrink and the stent, as a result, will not be in direct contact with the cells of the previously obstructed natural lumen.

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cris L. Rodriguez whose telephone number is (703) 308-2194. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 19, 2004


Cris L. Rodriguez
Examiner
Art Unit 3763


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700